



COVID 19 (nCorona) Virus Outbreak Control and Prevention State Cell

Health & Family Welfare Department

Government of Kerala

**COVID-19 – ADVISORY ON USING RAPID DIAGNOSTIC KITS FOR COVID-19
DIAGNOSIS AND SURVEILLANCE – Reg**

No.31/F2/2020/Health – 27th March 2020

WHO has declared the COVID-19 epidemic affecting more than 199 countries as a Pandemic. Due to the inflow of persons from affected countries, Kerala state has strengthened the surveillance and control measures against the disease.

The Expert Group had given recommendations regarding the role of rapid diagnostic kits in the diagnosis and surveillance of COVID-19

Recommendations

Diagnostic testing for SARS-CoV-2 is extremely important for its control. It is those countries that have tested the most people that have been able to contain the spread and mortality. When considering which test to use, we have to take into account the accuracy, cost, infrastructure and human resource available. The following approach may be considered.

1. Use PCR as the primary diagnostic modality
 - a. Set up testing facilities using Real Time PCR in as many centres as possible. The tests may be done in clinical and research laboratories that routinely offer PCR based tests. Machines from universities etc may be borrowed on a temporary basis to boost throughput.
 - b. Point of care cartridge PCR may be used in centres where it is available. This would be more useful in the peripheral centres like the TB control units
 - c. Private laboratories may be asked to contribute to the effort by helping to test the pool of patients identified by the public health authorities. They should be supplied reagents free for this purpose.
 - d. Free market testing may be discouraged as it will mainly be used by hypochondriacs with money to spare and waste resources.

ROLE OF ANTIBODY BASED RAPID TESTS

Antibody tests need not be used as a primary diagnostic test.

- a. It can however be used sparingly as an adjunct in doubtful cases negative for PCR and to test contacts for epidemiological purposes as needed.
 - b. The main use of the antibody test would be to study the incidence and prevalence of disease and local outbreaks by well-designed studies setting up surveillance centres.
 - c. They can be used in a limited manner to screen new arrivals from within or outside the country and those who test positive may be quarantined.
- Efforts should be obtained to procure FDA/ICMR approved rapid test kits which will help in disease surveillance.

THE ELIGIBILITY OF PRIVATE and GOVERNMENT LABORATORIES

1. NABL accredited laboratories
2. Laboratories approved by ICMR to do COVID 19 testing.
3. They will be given a dossier for online registration and online reporting of the test results. For any clarification and initial registration they may send the request on the following email address – covidpsnodedme@gmail.com
4. Use of Rapid Test Kits approved by FDA or ICMR only.
5. Detailed guidelines for the Laboratories are issued below.

Criteria for selection of a patient/person for COVID-19 Rapid Antibody Testing

1. The patient/person should have a prescription for COVID-19 testing issued by a registered medical practitioner.
2. Tests can be performed on persons who have returned from foreign countries or the contact of persons returned from the foreign countries.
3. Tests can be performed in COVID-19 suspects or symptomatic high risk contacts that were negative by RT-PCR.
4. Tests can be performed in high risk individuals like healthcare workers who work in COVID-19 designated treating facilities who are involved in direct care of COVID positive patients.
5. Tests can be done in a locality where a cluster of Severe Acute Respiratory Infection (SARI) cases without a diagnosis has been reported.
6. Tests can be performed on individuals who have recovered from SARI without a diagnosis.

SOPs for Management & Reporting Rapid Antibody Test for COVID-19 by the Laboratories:

1. The laboratories should have a **valid NABL accreditation** (Quality Council of India).
2. A **Medical officer** from the Laboratory should be identified as a **nodal person** for communications related to Rapid Diagnostic Testing for COVID-19.
3. The laboratory should **register online** for getting approval for initiating Rapid Diagnostic Test for COVID-19. The facilitation will be provided through the email ID covidpsnodedme@gmail.com on request.
4. Once they obtain registration from Govt. of Kerala they can start doing the Rapid Diagnostic Tests for COVID-19.
5. **ONLY** United States Food and Drug Administration (**US FDA**) or Indian Council For Medical Research (**ICMR**) approved Rapid Antibody kits for COVID-19 should be used for testing.
6. The testing should be done **only with a prescription** from a registered Medical Practitioner.
7. The category of people on whom Rapid Antibody Test can be done is as mentioned above.
8. All COVID-19 **transmission based precautions** should be taken into consideration while taking the samples, testing and while in contact with the patient. Full personal protective equipment should be worn before sampling, separate COVID testing corner without overcrowding should be ensured and mixing of suspected patients with other customers should be avoided. Good Laboratory Practices should be observed at all points.
9. Training for all personnel involved in the process (from COVID reception area, sampling, testing including security personnel) should be **trained in prevention of COVID-19**.
10. The test results should be **reported online (real-time)** in the format given in the **annexure-1**. The access to the online reporting portal shall be provided once the registration is complete.

11. The Nodal person in charge of COVID-19 rapid antibody testing should ensure **confidentiality and privacy** of reporting of results, safety of data, **Good Laboratory Practices** and the online facility provided for online reporting only.
12. Guidance on Rapid antibody kits for COVID-19 and availability of antibody based rapid kits approved by CE -IVD and ICMR are available on the ICMR website released on 27th March 2020. https://icmr.nic.in/sites/default/files/upload_documents/Guidance_on_RapidKits_COVID19_27032020.pdf


Principal Secretary

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CHARGE OF COVID-19 TESTING : _____												
	Name and Address of referring facility(Doctor and Instituti on or Voluntar y)	Specime n Type	Specime n ID	Date of taking the sample	Name of Test Kit Used	Batch number of Kit used	Whether the Rapid test kit used is approved by ICMR(Y/N)	Whether the Rapid test kit used is approve d by US FDA (Y/N)	IgM positive status	IgG positive status	Category of Positivity	